

What is claimed is:

1. A rotational molding system for molding a medical article comprising:
a multi-axis rotational molding machine; and
a mold mounted to said molding machine wherein the interior of said mold defines a cavity in the desired shape of the medical article to be molded.
2. The system according to claim 1 wherein said mold comprises first and second mold pieces matable to form a vacuum-tight seal along mating surfaces between said first and second pieces.
3. The system according to claim 1 wherein said mold comprises a sprue opening fluidly connected to said interior of said mold.
4. The system according to claim 2 wherein one piece of said mold has a hemispherical cavity shape.
5. The system according to claim 1 wherein said interior of said mold is sized to allow for the thickness of a liner to coat an inside surface of said mold.
6. A method for molding a medical article comprising the steps of:
inserting a molding material into a cavity within a mold;
applying a vacuum to said mold;

rotating said molding material in said mold about at least two axes to coat the interior of said mold cavity with said molding material.

7. The method of claim 6 further comprising the steps of:
inserting a liner material into said cavity;
rotating said liner material in said mold about at least two axes to coat the interior of said mold cavity with said liner material.
8. The method according to claim 7 wherein said liner material coats the interior of said mold cavity thereby masking any surface irregularities.
9. The method according to claim 7 wherein said liner material is a thermoplastic selected from the group consisting of polyethylene, polypropylene, nylon and fluoropolymer.
10. The method according to claim 7 wherein said liner material is a thermoset selected from the group consisting of polyester resin, polyurethane and epoxy.
11. The method according to claim 6 wherein said molding material is a room temperature acetoxycured silicone dispersion in a solvent.
12. The method according to claim 6 wherein said molding material is a platinum catalyzed heat-cured silicone dispersion in a solvent.

13. The method of claim 7 further comprising the step of separating said liner material from said molding material.
14. The method of claim 13 wherein said liner material is separated from said molding material by dissolving said liner material.
15. The method of claim 13 wherein said liner material is separated from said molding material by melting said liner material.
16. The method of claim 13 wherein said liner material is separated from said molding material by burning said liner material.
17. The method of claim 13 wherein said liner material is separated from said molding material by peeling said liner material from said molding material.
18. The method of claim 6 further comprising the step of removing the medical article from the mold through an opening in the mold left by a sprue.
19. The method of claim 6 further comprising the step of inserting a filler material into said mold cavity.
20. The method of claim 19 further comprising the step of curing said filler material.

21. A system for rotationally molding a medical article comprising:
- means for rotating a mold about at least two axes;
 - means for molding a material within said mold into the form of the medical article;
 - means for inserting a molding material into said mold; and
 - means for supplying vacuum to said mold.
22. The system of claim 21 further comprising means for inserting a liner material into said mold.
23. A multi-axis rotationally molded medical article comprising:
- a shell defining an interior cavity;
 - said shell being formed of at least one layer of a silicone selected from the group consisting of room temperature acetoxo-cured silicone and platinum catalyzed heat-cured silicone, and tin catalyzed silicone.
24. The medical article of claim 23 wherein said shell is textured.
25. The medical article of claim 23 wherein said shell is seamless.
26. The medical article of claim 23 wherein said shell is patchless.

27. The medical article of claim 23 where said shell has a thickness of from about 0.005 inches to about 0.06 inches.
28. The medical article of claim 23 further comprising a filler material contained within said interior cavity.
29. The medical article of claim 28 wherein said filler material is a silicone gel.
30. The medical article of claim 28 wherein said filler material is a saline solution.
31. The medical article of claim 28 wherein said filler material is a foam.
32. The medical article of claim 23 further comprising a removable liner.
33. The medical article of claim 31 wherein said liner is a thermoplastic selected from the group consisting of polyethylene, polypropylene, nylon and fluoropolymer.
34. The medical article of claim 31 wherein said liner is a thermoset selected from the group consisting of polyester resin, polyurethane and epoxy.
35. The medical article of claim 23 wherein said article is a medical implant.
36. The medical article of claim 35 wherein said article is a breast implant.

37. The medical article of claim 23 wherein said article is an elastomeric balloon.
38. The medical article of claim 23 wherein said article is a catheter balloon.